UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: Bair Hugger Forced Air Warming Products Liability Litigation

MDL No. 15-2666 (JNE/FLN)

This Document Relates To:
ALL CASES

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF THOMAS KUEHN, PH.D.

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I. INTRODUCTION

Plaintiffs' motion to exclude the opinions and testimony of Thomas Kuehn, Ph.D. misunderstands his role and his work in this case. Professor Kuehn is an expert in the filtration of bioaerosols. As his report makes clear, Prof. Kuehn will explain the mechanics of how air filters trap particles, including bacteria, and rebut Plaintiffs' allegation that the filters used in Bair Hugger warming units are inadequate for their intended purpose. Although Plaintiffs question the effectiveness of the Bair Hugger filters, they have not designated an expert in filtration: their HVAC[1] engineer, Daniel Koenigshofer, has never tested an air filter to determine its "efficiency" (how well it captures particles), and he claims no expertise with the industry standard—ASHRAE 52.2—that applies to such testing. Koenigshofer Dep. (ECF No. 810-1 at 160–184) at 81:15–21. By contrast, Prof. Kuehn was a member of the ASHRAE committee that oversaw the 52.2 standard for many years.

Rather than engage Prof. Kuehn on filtration issues, Plaintiffs focus their attack on Kuehn's observation that Plaintiffs' computational fluid dynamics expert, Prof. Said Elghobashi, supplied an excessively high temperature for use in Plaintiffs' computer model. Plaintiffs' attack on Prof. Kuehn's observation is misplaced and unfounded.

As Defendants noted in their motion to exclude his testimony, Prof. Elghobashi assumed that jets of hot air measuring 41ºC (106ºF) shoot out from the surgical drapes covering the Bair Hugger blanket. ECF No. 805 at 38-39. To test this assumption, Prof.

[1] "HVAC" is an acronym for "heating, ventilation, and air conditioning."

Kuehn took temperature measurements at various points around a draped mannequin. With the Bair Hugger system on, he took numerous readings for more than an hour, and never found a temperature higher than 75 degrees—well below Prof. Elghobashi's assumed temperature of 106 degrees for the entire perimeter of the surgical drapes.

Plaintiffs take issue with Prof. Kuehn's approach to the measurements, arguing that he should have precisely simulated the airflow of an operating room before proceeding to take them. Ironically, however, Prof. Elghobashi *took no measurements at all* to verify his assumed temperature of 106 degrees. Plaintiffs also complain that Prof. Kuehn's temperature measurements "lack methodology" and "cannot be reproduced," Pl. Mem. at 17, but these were simple instrument readings that any engineer could easily repeat. Indeed, Prof. Elghobashi agrees that temperature measurements were "necessary" to support his assumption, but instead of taking measurements he "substituted by thinking hard." Elghobashi Dep. (ECF No. 810-2 at 146-155) at 114:4–115:8.

Plaintiffs must prove the validity of the assumptions that Prof. Elghobashi fed into their computer model, and Prof. Kuehn's temperature measurements demonstrate their burden has not been met. In fact, no expert on either side has been able to validate Prof. Elghobashi's assumption. This is not an inconsequential error; as Prof. Kuehn points out, "correcting this error in boundary condition will result in airflow that does not change nearly as much when the Bair Hugger is operated as in the results presented." Expert Report of Thomas Kuehn, Ph.D. ("Kuehn Rpt.") (DX1)[2] at 12. In other words, Prof.

[2] All exhibits are attached to the Declaration of Benjamin W. Hulse filed concurrently.

Elghobashi's exaggeration of the temperature around the drape is wholly responsible for the "turbulence intensity" displayed in Plaintiffs' computer model, which is one of the two bases—along with McGovern's infection rate comparison—for Plaintiffs' entire general causation case. Because Plaintiffs' computer model relies on a false assumption for a critical input, it must be disregarded. *See Pallano v. The AES Corporation*, 2016 WL 750432, at *6 (Del. Super. Ct. 2016) (excluding computational fluid dynamics model based on expert's use of "erroneous values.").

Prof. Kuehn's opinions are based on his substantial training and experience in filtration, which none of Plaintiffs' experts can match or even approach. As a rebuttal expert, it is entirely appropriate for Prof. Kuehn "to critique plaintiffs' expert's methodologies and point out potential flaws in the plaintiff's experts' reports." *Aviva Sports, Inc. v. Fingerhut Direct Marketing, Inc.*, 829 F. Supp. 2d 802, 835 (D. Minn. 2011). Prof. Kuehn's rebuttal opinions and testimony are relevant and reliable under *Daubert* and Rule 702, and they meet *Goeb v. Tharaldson*'s requirements for general acceptance and foundational reliability. Plaintiffs' motion to exclude Prof. Kuehn's opinions and testimony should therefore be denied.

II. FACTS

Thomas Kuehn is a Professor Emeritus of Mechanical Engineering at the University of Minnesota. Over his long and distinguished career, he has researched and written extensively in the areas of HVAC engineering, indoor environments, clean spaces, filtration, and bioaerosols. He is the lead author of THERMAL ENVIRONMENTAL ENGINEERING (Prentice Hall 3rd ed.), one of the few textbooks on this subject. Kuehn Rpt.

(DX 1) at 1. Prof. Kuehn has been an active member of the American Society of Heating, Refrigeration, and Air Conditioning Engineers ("ASHRAE")—the organization that promulgates HVAC standards—for 25 years, and has served on several ASHRAE leadership committees, including the Technical Council that oversees the ASHRAE 52.2 standard for evaluating and rating filter efficiency. *Id*. at 1–2.

Prof. Kuehn also co-founded the Center for Filtration Research at the University of Minnesota, where he has studied such issues as the efficiency of filters based on media type and particle loading; growth of captured bioaerosol particles on clean and loaded filters; and the influence of environmental factors such as temperature, humidity, and airflow rate on filter performance. *Id.* at 2. He designed, built, and oversaw the operation of a test facility at the University of Minnesota to study the performance of air filters in capturing aerosolized bacteria, fungi, and viruses. *See id.*

Prof. Kuehn reviewed numerous documents and data in forming his opinions for this case. These materials include relevant literature and scientific studies, Arizant and 3M internal documents and test reports, and several of Plaintiffs' expert reports. *See id.* at 2, Ex. A. He also reviewed the deposition testimony of Karl Zgoda (a former Arizant and 3M engineer involved in filter decisions) and Dr. Robert Crowder (a corporate representative from Pentair, Arizant and 3M's filter supplier) regarding the history of the filter media used in the Bair Hugger warming units, as well as test results reflecting the minimum efficiency rating value (MERV) of filters currently used in all Bair Hugger models. *See id*. at 2.

In addition to his thorough review of documents and data concerning the Bair Hugger filters, Prof. Kuehn also took airflow velocity and temperature measurements around a mannequin prepped and draped with a Bair Hugger blanket (in the same manner as for a hip replacement surgery). Prof. Kuehn used a freshly calibrated hot-wire anemometer to take airflow and temperature measurements at different locations around the draped mannequin. *See* Kuehn Rpt., Ex. C. As noted, the highest temperature Prof. Kuehn measured was just under 75 degrees—markedly lower than the 106 degrees that Prof. Elghobashi assumed for the entire perimeter of the surgical drapes. *See id.* Thus, he concluded that "the assumed thermal buoyancy of the warm air leaving the blanket is more than a factor of 5 too large [in Elghobashi's assumption] as thermal buoyancy is linearly related to temperature difference." In other words, because the difference in temperature between the drape edge and the room air is much lower than Prof. Elghobashi assumed, the upward air currents shown in Plaintiffs' computer model are greatly exaggerated.

Prof. Kuehn's efforts to obtain actual temperature measurements stand in stark contrast to Plaintiffs' experts, none of whom bothered to try.[3] Prof. Kuehn's measurements

[3] With the possible exception of Plaintiffs' biomedical engineering expert, Dr. Yadin David. Dr. David attempted to measure the air temperature under a Bair Hugger blanket (not a draped mannequin) on a test bench. Report of Dr. Yadin David (ECF No. 316) at 15. The highest temperature Dr. David found *directly under the blanket* was 36ºC (97ºF). *See id.* Dr. David did not attempt to measure the temperature of the air escaping the sides of a surgical drape over the Bair Hugger blanket, which was the scenario for Prof. Elghobashi's assumption of 41ºC (106ºF)). The air exiting the sides of the drapes would obviously be cooler than the air trapped under the blanket—yet Dr. David could not even replicate Prof. Elghobashi's assumed temperature for the air *under* the blanket.

thus supply relevant and useful data to fill the gaps created by Plaintiffs' unverified assumptions.

Prof. Kuehn's report explains filtration concepts generally, including the efficiency and function of fibrous filters like those used in Bair Hugger warming units, and how filter efficiency is measured using ASHRAE standards. *See id.* at 2–8. He opines that "the Bair Hugger filters are effective at removing airborne bacteria from the air that passes through them and are therefore appropriate for use in the operating room." *Id.* Prof. Kuehn notes that a filter media used in older Bair Hugger units "had greater efficiency in the 0.3-1 micron particle size range," but he points out that "particles that carry infectious bacteria are generally larger than 1 micron." *Id.* He further opines that "[t]he Bair Hugger's incorporation of a MERV 14 filter—the same minimum filtration level that ASHRAE recommends for air supplied to operating rooms—provides additional protection from airborne bacteria for patients undergoing surgery." *Id.* at 8–9. He concludes that the filter media currently used in the Bair Hugger system, rated at MERV 14, "is *fully capable of capturing bacteria* and the particles that carry them." *Id.* at 8 (emphasis added).

III. ARGUMENT

A. Prof. Kuehn Is Qualified to Offer the Opinions in His Report.

Plaintiffs contend that Prof. Kuehn is not qualified to offer the opinions in his report, Pl. Mem. at 13–14, but they cannot dispute that his filtration credentials are sterling. He conducts filtration research. He built a filter efficiency test facility. He has been an active member of ASHRAE—the organization that sets air filtration standards—for 25 years. Any suggestion that Prof. Kuehn is unqualified to render opinions about filtration can be

dismissed out of hand. To the extent Plaintiffs argue that Prof. Kuehn has testified beyond his credentials, they are to blame for questioning him on topics pertaining to orthopedic surgery, microbiology, infectious diseases, and other areas in which he claims no expertise.

B. Plaintiffs Concede that Prof. Kuehn's Opinions Regarding Bair Hugger Filtration Are Reliable.

Plaintiffs do not take issue with Prof. Kuehn's opinions that MERV 14 filtration is effective at controlling bacteria; that ASHRAE's requirement of MERV 14 filtration for operating rooms is appropriate; or that the Bair Hugger filters have been tested according to ASHRAE standard 52.2 and shown to meet or exceed MERV 14. Nor do they question Prof. Kuehn's review of historical Bair Hugger filter specifications, which never called for an efficiency level less than MERV 14 in either the 500 series or 700 series warming units. These are Prof. Kuehn's core opinions to which he will testify at trial, and Plaintiffs' failure to take them on demonstrates that they are unshakeable.

C. Prof. Kuehn's Approach to His Temperature Measurements Was Appropriate.

Plaintiffs level a series of misleading and irrelevant attacks on Prof. Kuehn's temperature measurements, all of which should be disregarded. First, Plaintiffs falsely claim that Prof. Kuehn did not disclose how he went about his measurements. *See* Pl. Mem. 16. But in fact he did:

> Measurements of air velocity below a Model 775 Bair Hugger mounted approximately 2 ft. above the floor indicated that there was no measurable difference between the air velocity near the floor when the Bair Hugger was off or turned on. Velocity measurements were also made at three locations near the edge of the blanket where the warm air escapes into the room.

Kuehn Rpt. (DX1) at 9–10. Prof. Kuehn provides additional information, including photographs, explaining where he took the measurements, and the anemometer's readings at each location in Exhibit C to his Report. *See id.*, Ex. C. As noted, based on these measurements, Prof. Kuehn opines that Dr. Elghobashi's assumed "boundary condition" of 41ºC (106ºF) at the drape edge—including where it meets the floor—is incorrect. *See id.* at 12.

Plaintiffs next argue that Prof. Kuehn's critique of Prof. Elghobashi's boundary conditions is invalid because he took his readings in a room that was not identical to a hospital operating room, and because he failed to account for the potential influence of a slight change in the room's thermostat setting. *See* Pl. Mem. at 4. But Plaintiffs fail to explain how these factors would matter. And as Prof. Kuehn explained at his deposition, the purpose of taking the measurements was for him to gain first-hand experience with the airflow dynamics in a room with the Bair Hugger on; this does not require the room to be identical to a hospital operating room. Prof. Kuehn's purpose was to measure the air velocity going into the unit and coming out of the blanket. Factors such as the type of room, room configuration, lights, or presence of surgical staff have little influence on these parameters. Kuehn Dep. (DX2) at 329:17–334:14. Moreover, Prof. Kuehn explains that the measurements were "intended to be a preliminary study to get some reasonable data," given that Prof. Elghobashi supplied no temperature data of his own. *See* Kuehn Dep. (DX2) at 333:17–334:6. Again, Prof. Kuehn is the only expert to have actually taken measurements of the temperature variations surrounding a draped Bair Hugger blanket;

Prof. Elghobashi simply assumed one temperature for the entire area around the surgical drapes.

D. Plaintiffs' Attacks on Prof. Kuehn's Opinions Are Based on Mischaracterizations of His Testimony.

Plaintiffs base much of their argument on misrepresentations, inaccuracies, and testimony taken out of context. Here are two examples:

Plaintiffs' Claim	What Prof. Kuehn Actually Said
Kuehn agrees that the air underneath the operating table has a greater concentration of bioburden than other areas in the operating room. Pl. Mem. at 6.	Q. What do you think has a larger bioburden, the air coming out of the ceiling or the air underneath the operating room table? A. I have no basis to make an opinion on that. Q. Okay. So sitting here today, you can't use your -- you can't use science and your engineering education to determine, based on the airflow in an operating room, whether or not the air coming out of the ventilation system has a greater or lesser bioburden than the air where there are a patient and three or four people standing around a surgical table. A. Well I -- I cannot rely on any data, but I can speculate that it would be -- the concentration would be higher under the table. Kuehn Dep. (DX 2) at 182:11–24.
Kuehn is unaware of any other device in the operating room that produces more watts of heat around the patient than the Bair Hugger does. Pl. Mem. at 6.	Q. You agree with me that the Bair Hugger produces more watts of energy than any other device in the operating room; correct? A. I -- I'm not aware of what other equipment would -- what -- what the heat loads of other equipment in the operating room would be. Kuehn Dep. (DX 2) at 208:15–21.

Plaintiffs' most egregious distortion is their contention that Dr. Kuehn "agrees that particles will travel from the blower to the blanket, that some of these particles will leave

the blanket, and that some of the particles that leave the blanket will contain bacteria." Pl. Mem. at 6. First, Prof. Kuehn has already stated in his report that the Bair Hugger's MERV 14 filter is "*fully capable of capturing bacteria* and the particles that carry them." Kuehn Rpt. (DX1) at 8. Second, the context of the questioning Plaintiffs cite for this "admission" concerns whether *the blanket* acts as a secondary filter:

> Q. Do you believe that the blanket can prevent -- Is there anything within the blanket that protects bacteria from coming out of the – the perforations?
>
> A. Because the blanket is made of a non-metallic -- I'm not sure the exact material, and there's a large surface area within the blanket, I would think there would be some – some deposits within the blanket itself before the particle leaves the holes, yes.
>
> Q. Okay. But some particles will leave the holes.
>
> A. Some particles will leave the holes, yes.

Kuehn Dep. (DX2) at 327:12–25. In this manner, Plaintiffs have misrepresented Prof. Kuehn's testimony regarding *the blanket*'s ability to trap particles as an "admission" regarding the performance of the *filter*. Prof. Kuehn's testimony should not be excluded or limited based on half-truths like this.

E. Prof. Kuehn's Opinions and Testimony Are Generally Accepted and Satisfy the Requirements of Minn. R. Evid. 702.

In addition to a showing that expert testimony is reliable and relevant, Minnesota law further requires that an expert's opinions be "generally accepted" in the relevant scientific community. *See Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000). Prof. Kuehn's testimony satisfies these standards. As set forth above, his opinions and testimony are based on a thorough review of relevant literature, 3M and Arizant documents, and applicable ASHRAE standards. ASHRAE provides the benchmark for ventilation and

filtration in United States hospitals and, clearly, its standards are "generally accepted" in the community of HVAC engineers, including those who design HVAC systems for operating rooms. Prof. Kuehn's testimony is therefore admissible under Minnesota law in addition to federal law.

IV. CONCLUSION

Prof. Kuehn's opinions and testimony are reliable, relevant, and effectively rebut Plaintiffs' accusations regarding the efficiency of the Bair Hugger system's filters. Moreover, his temperature measurements are adequately disclosed in his report, and could easily have been performed by Plaintiffs' experts, including Prof. Elghobashi, had they chosen to do so. Prof. Kuehn's opinions and testimony satisfy the requirements of both federal and Minnesota law. His testimony should be allowed, and Plaintiffs' motion should be denied.

Dated: October 3, 2017

Respectfully submitted,

/s/ Benjamin W. Hulse

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